SAT Report

PMN Number: **P-11-0110**
SAT Date: **12/21/2010**
Print Date: **8/19/2014**

Related cases: [redacted]

Concern levels:

Type of Concern:	**Health**	**Eco**	**Comments**
Level of Concern:	2	3	**Health: ; Eco:** High for Fish ChV only

Persistence	**Bioaccum**	**Toxicity**	**Comments**
1	1	1	
		Awaiting Human Health Entry	
		Awaiting Human Health Entry	
		Awaiting Human Health Entry	

Exposure Based Review:

Health: No
Ecotox: Yes **Exposure based testing (eco):** WS, then Fish Chronic only

Routes of exposure:

Health: Dermal Inhalation
Ecotox: All releases to water
Fate: ;

Keywords:

Keywords:

Summary of Assessment:

Fate:

Fate Summary: P-11-0110 = T-11-0004
FATE: Estimations for neutralized cation MW 369 [redacted]
log Kow = 7.35 (E)
log Koc = 5.36 (E)
log Fish BCF = 3.36 (E)

log Fish BAF = 1.65 (E)

[redacted]

POTW removal (%) = 90 via sorption and biodeg
Time for complete ultimate aerobic biodeg = wk-mo
Sorption to soils/sediments = v.strong
PBT Potential: P1B1
*CEB FATE: Migration to ground water = negl

Health:

Health Summary: Absorption is nil through the skin, poor through the GI tract, and moderate through the lungs based on analogs. There is concern for irritation to all exposed tissues based on the [redacted] moiety. There is also concern for lung effects if respirable [redacted] are inhaled based on interference with the natural surfactants in the lungs. Moderate concern.

Ecotox:

Test Organism	Test Type	Test End Point	Predicted	Measured	Comments
fish	**96-h**	**LC50**	*		
daphnid	**48-h**	**LC50**	*		
green algal	**96-h**	**EC50**	*		
fish	**_**	**chronic value**	0.0006		OR *
daphnid	**_**	**chronic value**	*		
algal	**_**	**chronic value**	*		
Sewage Sludge	**3-h**	**EC50**	**_**		
Sewage Sludge	**_**	**Chronic Value**	**_**		

Ecotox Values Comments: High for Fish ChV only - all other values are NES

Factors	Values	Comments
Assessment Factor	10	
Concentration of Concern (ppb)	1	
SARs	[redacted]	
SAR Class	[redacted]	
Ecotox Category		

Ecotox Factors Comments:

SAT Chair: Becky Jones

Focus Report

New Chemicals Program

PMN Number: **P-09-0447**

Focus Date:	07/26/2009 11:00:00 PM	Report Status:	Completed
Consolidated Set:	P-09-0447; P-09-0448		
Focus Chair:	Darlene Jones	Contractor:	Christina Stanley

I. Notice Information

Submitter: [redacted] CAS Number: [redacted]

Chemical Name: [redacted]

Use: [redacted].STN file CA: No references were found. Consolidated set: P-09-447-48.

Other Uses: [redacted]

PV-Max: [redacted]

Manufacture: X Import:

II. SAT Results

(1) **Health Rating:** 1-2 **Eco Rating:** 2 **Comments:** ;

Occupational: 1C **Non-Occupational:** 3 **Environmental:** 3

(1) **PBT:** 2 2 1 **Comments:**

III. OTHER FACTORS

Categories:

Health Chemical Category: Ecotox Category: [redacted]

Related Cases/Regulatory History:

Health related Cases: [redacted]

Ecotox Related Cases: Analogs: [redacted].

Regulatory History:

[redacted] PENDING 5(e)C ORDER DEVELOPMENT EXPOSURE-BASED

MSDS/Label Information:

MSDS: Yes Label: No

General Equipment: [redacted]

Exposure Based Information:

Exposure Based Review: Y	Exposure Based Review (Health): N
Exposure Based Review (Eco): Y	Exposure Based (Occupational): No
Exposure Based Review (Non Occupatuional):	Exposure Based (Environmental):

IV. Summary of SAT Assessment

Fate:

Fate Summary: P-09-0447-48

FATE: [redacted]

[redacted]
log Kow = 4.37 (E);
[redacted]
VP < 1.0E-6 torr at 25 EC (E)
BP > 400 EC (E)
H = 2.42E-6 (E)
log Koc = 4.47 (E)
log Fish BCF = 1.85 (E)
log Fish BAF = 3.17 (E)
POTW removal (%) = 50 via sorption
Time for complete ultimate aerobic biodeg = wk-mo
Sorption to soils/sediments = strong
Volatilization half-life from a standard river = 480 hrs
Volatilization half-life from a standard lake = 220 da
Atmospheric Oxidation Half-life = 1.6 hr via OH radical
Atmospheric Oxidation Half-life = 2.1 hr via ozone
PBT Potential: P2B2
*CEB FATE: Migration to ground water = negl - slow

Health:

Health Summary: Absorption is nil through the skin based on physical/chemical properties, poor through the GI tract based on analogs, and moderate through the lungs based on analogs. There is concern for lung effects through [redacted] if respirable [redacted] are inhaled and concern for irritation to all exposed tissues based on [redacted]. There is also uncertain concern for developmental toxicity based on summary data provided in the submission for the analog, [redacted], which seemed to cause more effects in mice (litter loss at 300 mg/kg) than in other species. In repeated dose studies, the analogs included in the submission showed low toxicity with NOELs of about 200 mg/kg with non-specific effects such as reduced weight gain at higher doses. Low moderate concern.

Ecotox:

Ecotox Values:

Fish 96-h LC50:	11(P)
Daphnid 48-h LC50:	2.4(P)
Green algal 96-h EC50:	5.6(P)
Fish Chronic Value:	1.7(P)
Daphnid ChV:	0.37(P)
Algal ChV:	0.95(P)

Ecotox values comments: Predictions are based on SARs for [redacted]; SAR chemical class = [redacted]; pH7; effective concentrations based on 100% active ingredients and mean measured concentrations; hardness <180.0 mg/L as CaCO3; and TOC <2.0 mg/L;

Ecotox Factors:

Assessment Factor:	10
Concern Concentration:	37

V. Summary of Exposures/Releases

Engineering Summary: P-09-0447

Exposures/Releases	Release	Release	Release
Scenario	**MFG: PMN Substance**	**PROC/USE 1: Oil Well Recovery** [redacted]	**PROC/USE 1: Oil Well Recovery** [redacted]
Sites	[redacted]	[redacted]	[redacted]
Media	[redacted]	[redacted]	[redacted]
Descriptor A	Conservative	High End	Output 2
Quantity A (kg/site/day)	[redacted]	[redacted]	[redacted]
Frequency A (day/year)	[redacted]	[redacted]	[redacted]
Descriptor B			
Quantity B (kg/site/day)			
Frequency B (day/year)			
From	[redacted]	[redacted]	[redacted]
Workers			
Exposure Type			

Engineering Summary: Exposures/Releases	Release	Release	Release
Scenario	**PROC/USE 1: Oil Well Recovery** [redacted]	**PROC/USE 2: Oil Well Recovery** [redacted]	**PROC/USE 2: Oil Well Recovery** [redacted]
Sites	[redacted]	[redacted]	[redacted]
Media	[redacted]	[redacted]	[redacted]
Descriptor A	Conservative	Output 2	Conservative
Quantity A (kg/site/day)	[redacted]	[redacted]	[redacted]
Frequency A (day/year)	[redacted]	[redacted]	[redacted]
Descriptor B			
Quantity B (kg/site/day)			
Frequency B (day/year)			
From	[redacted]	[redacted]	[redacted]
Workers			
Exposure Type			

V. Summary of Exposures/Releases

Engineering Summary: P-09-0447

Exposures/Releases	Exposure	Exposure	Exposure
Scenario	**MFG: PMN Substance**	**PROC/USE 1: Oil Well Recovery** [redacted]	**PROC/USE 2: Oil Well Recovery** [redacted]
Sites	[redacted]	[redacted]	[redacted]
Media	**Dermal**	**Dermal**	**Dermal**
Descriptor A	High End	High End	High End
Quantity A (kg/site/day)	[redacted]	[redacted]	[redacted]
Frequency A (day/year)	[redacted]	[redacted]	[redacted]
Descriptor B			
Quantity B (kg/site/day)			
Frequency B (day/year)			
From	[redacted]	[redacted]	[redacted]
Workers			
Exposure Type	[redacted]	[redacted]	[redacted]

VI. Focus Decision and Rationale

Regulatory Actions

Regulatory Decision: PMN Ban Pending Upfront Testing Decision Date: 07/26/2009
Type of Decision:

Rationale: P09-0447-0448 will be regulated under 5(e) category [redacted] under the risk and exposure based authorities for ecotoxicity and fate concerns. Human health concerns were low-moderate and risks were mitigated by adequate dermal protection and negligible inhalation exposure. Ecotoxicity concerns are from releases to water where the chronic 37 ppb COC was exceeded 50 of [redacted] days per year (SWC: [redacted]) during manufacturing and 45 of [redacted] days per year (SWC: [redacted]) during processing/use. The acute COC of 480 ppb was also exceeded during processing/use 1 (SWC: [redacted]) and during processing/use 2 (SWC: [redacted]). The following EAB exposure based criteria were met: Drinking (Surface) Water Dose ([redacted]); Fish Ingestion Dose ([redacted]); Surface Water Release After Treatment ([redacted]) and Total Release After Treatment ([redacted]). Ecotoxicity testing will be the base set, Fish acute toxicity test (OPPTS: 850.1075), Aquatic Invertebrate acute toxicity test freshwater daphid (OPPTS: 850.1010), and algal toxicity tiers I and II (OPPTS: 850.5400). Fish and daphnia testing will be done using the flow-through method and the static method will be used for algal. A certificate of analysis is required of the submitter and it is recommended that a RAD representative approve all protocols before beginning testing. Fate testing will be the ready biodegradability (OPPTS 835.3110). No human health testing is required. The required testing will address both the risk and exposure based concerns.

Summary of Exposures and Releases:
Manu:

[redacted]

Proc/Use#1:

[redacted]

[redacted]:

[redacted]

Proc/Use#2:

[redacted]

[redacted]:

P2 Rec Comments:

Testing:

Final Recommended:

Health:

Eco: Fish acute toxicity test (OPPTS: 850.1075), Aquatic Invertebrate acute toxicity test freshwater daphid (OPPTS: 850.1010), and algal toxicity tiers I and II (OPPTS: 850.5400)

Fate:

Other:

Briefing Paper

Case Number: **P-09-0447**
Hybrid: Risk- and Exposure-Based
Risk Based Ecotoxicity; Exposure based Ecotoxicity; Risk based Fate; Exposure based Fate

Part I: Background Data

Program Manager: Kristan Markey
Technical Integrator:
Review Team: Audrey Binder, Gordon Cash, Gregory Macek, Ken Moss, Robert Boethling, Sharon Austin
Meeting Date: 01/18/2012
Day In Process: 90
Day 90: 12/31/2012

A. CBI Claims: Chemical ID, Company, Uses, Production Volume, Processes, Chemical Composition, Formulation, Use Sites

B. Submitter: [redacted]

C. Chemical Identity: [redacted]
[P-09-0448]

D. Chemical Class:
Ecotox: [redacted]

E. Structure:

[redacted]09-0447

[redacted]

P-09-0448

[redacted]

F. Physical/Chemical properties:

VP: Measured Torr @ 25 C
Est. <0.000001 Torr @ 25 C
s-H2O: Measured g/L
MW: [redacted]
Phys State: Neat: Solid
Manufacturing: [redacted]
Process/Form: [redacted]
End Use: Used as formulated; [redacted]

G. Volume:

H. Use: [redacted]r [redacted]).STN file CA: No references were found. Consolidated set: P-09-447-48.

I. Test Data Submitted: None

J. MSDS:

MSDS: Yes Label: No

General equipment: suitable protective clothing / use impervious gloves/ chemical goggles/ face shield / general ventilation/ local exhaust is suggested for use, where possible, in enclosed or confined spaces.

Respirator: if ventilation is not sufficient to effectively prevent buildup of aerosols or vapors, appropriate NIOSH/MSHA respiratory protection must be provided.

Health Effects: may cause irritation to eyes and skin / inhalation of vapors or mists of the product may be irritating to the respiratory system.

K. SAT Ratings:

Human Health: 1-2 ; Environment: 2 ;

L. Focus Results: P09-0447-0448 will be regulated under 5(e) category [redacted] under the risk and exposure based authorities for ecotoxicity and fate concerns. Human health concerns were low-moderate and risks were mitigated by adequate dermal protection and negligible inhalation exposure. Ecotoxicity concerns are from releases to water where the chronic 37 ppb COC was exceeded 50 of [redacted] days per year ([redacted]) during manufacturing and 45 of [redacted] days per year (SWC: [redacted]) during processing/use. The acute COC of 480 ppb was also exceeded during processing/use 1 (SWC: [redacted]) and during processing/use 2 (SWC: [redacted]). The following EAB exposure based criteria were met: Drinking (Surface) Water Dose ([redacted]); Fish Ingestion Dose ([redacted]); Surface Water Release After Treatment ([redacted]) and Total Release After Treatment [redacted] Ecotoxicity testing will be the base set, Fish acute toxicity test (OPPTS: 850.1075), Aquatic Invertebrate acute toxicity test freshwater daphid (OPPTS: 850.1010), and algal toxicity tiers I and II (OPPTS: 850.5400). Fish and daphnia testing will be done using the flow-through method and the static method will be used for algal. A certificate of analysis is required of the submitter and it is recommended that a RAD representative approve all protocols before beginning testing. Fate testing will be the ready biodegradability (OPPTS 835.3110). No human health testing is required. The required testing will address both the risk and exposure based concerns.

Summary of Exposures and Releases:

Manu:

[redacted]

Proc/Use#1:

[redacted]

[redacted]

Proc/Use#2:

[redacted]

Part II: New Information

These cases have undergone extensive discussion and review over a three-year period. See the attached summary of the case for an extensive discussion of the history. P080512-513_Summary of case to date 11092011.doc

For P-09-0447 and 448, the toxicity and exposure issues are straightforward. The company requested that EPA consider toxicity testing for [redacted] (another submission from the Company that has subsequently been withdrawn) a structurally appropriate analog for P-09-0447 and 448. RAD agreed and lowered the acute CoC to 200 ppb and ChV to 10 ppb for both compounds. There are no complicated fate issues with respect to the substances.

From a toxicity and exposure standpoint:

[redacted]

[redacted] that is present in the final product at 3%, and per EPA's review of the case, a potential initial degradant. The chemical structure of [redacted], but

with the [redacted]

[redacted]

From the initial review and action letter, EPA found:

Property	[redacted]	[redacted]
Chronic CoC	1 ppb	15 ppb
Acute CoC	No effects at saturation	320 ppb (see action letter)
Expected SWC during processing	5 ppb (contamination only, did not evaluate degradation). Exceeds CoC for 18 days	900 ppb. Exceeds the CoC for 41 days/year
Expected SWC during use 1	Not computed	15,000 ppb acute
Expected SWC during use 2	Not computed	2400 ppb acute

EPA originally expected additional amounts of [redacted] to be produced as the first step of biodegradation of [redacted] that may lead to an increase in the risk to the environment due to additional amounts of [redacted] being released to surface waters. Furthermore, in evaluating the chemical structure of the PMNs, the Agency is not able to predict which side of the PMN substances (nominally the [redacted]" side) will degrade more quickly. Based on SARs for both PMNs, the Agency predicts greater ecotoxicity from the [redacted] side of the PMN substances.

At an early stage, the Company requested alternatives to EPA's standard tiered testing approach in order to save the Company time and money. Because of the complexity of the molecule, EPA agreed. The first approach, a radiolabelled biodegradation study, was rejected by the Company as being unfeasible (expensive and nearly impossible to synthesize sufficient quantities of the radiolabelled substance).

EPA also indicated it would consider a river die away type approach. This approach combines a biodegredation study and toxicity test. The Company provided a protocol, which EPA reviewed and provide comments on, the primary one being that the Company should not only test the toxicity of the degredant, but should also conduct analytical sampling on the liquor. The Company rejected this analytical approach as being an "academic study."

There are a number of releases that have been assessed for all the substances. CEB has spent over 5 hours working directly with the Company to address these releases and collect additional information. The Company has been unable to persuade CEB that its approach will mitigate all releases.

The outstanding releases are:

- Releases during manufacturing - The Company proposed an approach that would involve multiple sampling and ultimate [redacted]
- Releases during [redacted] - CEB does not agree that a submitter is able to control where [redacted]
- Releases during processing/use: the substances are [redacted]. CEB did not agree that the submitter has any reasonable knowledge that all substances are [redacted] would not result in water releases.

As of November 2011, the company has provided assurances that all releases would be mitigated including:

- [redacted].
- [redacted]
- [redacted]
- [redacted]

The Company objected to any testing or a processor order approach. They have been unable/unwiling to provide any customer specific information. A similar case [redacted] withdrawn in face of 5(e) and resubmitted as [redacted], included testing and extensive customer details.

In December 2011, the Company provided additional information regarding transport of their substances. Specifically, the Company will [redacted] of the PMN substances during transport. The [redacted]:

1. [redacted]
2. [redacted]
   a. [redacted]
   b. [redacted]
   c. [redacted].
3. [redacted]
   a. [redacted];
   b. [redacted]
   c. [redacted]

Finally, a recent conversation with [redacted] indicated that modern techiques allow straightforward identification of the degradants, especially for non-PFC substances. These groups are willing to consult with the PMN submitter. [redacted] has also indicated potential interest in working with [redacted] to complete the river die-away testing.

In August 2012, the Company provided significant comments back regarding the proposed consent order. During the meetings with technical staff, EAB and RAD agreed to re-review test data that was originally submitted with [redacted]. They accepted the premise that this data showed that the [redacted] substance biodegrades to substances that present no acute or chronic toxicity, but will use default ecotoxicity instead, for the biodegraded liquor (1000 ppb for the chronic CoC, 20,000 ppb for the acute CoC). Based on the chemical similarity, they have accepted that this data applies to [redacted]

NMCB also met with CEB to review the remaining outstanding issue with regards to [redacted]. In working with CEB, we agreed that with a consent order in place with a regulatory trigger (either a no release to water or limit) could serve as a basis for revising an engineering report. See the attached policy document.

Part III: Recommendation and Rationale

The PM recommends the development of a 5(e) consent order for P-09-0447/448 holding the Company to their committments including:

- Regulatory trigger of 10ppb for releases to water.

Based on the outstanding testing and as a policy for such consent orders, the PM recommends triggering the chronic set of ecological testing for P-09-0447/448 as detailed in RAD's July 12, 2010 memo (fish early life stage test (OPPTS 850.1400) and a daphnid chronic toxicity test (OPPTS 850.1300)) on P-09-0448 (the more toxic of the substances)

For [redacted], the PM recommends a SNUR requiring all releases from manufacturing, processing, and use are injected to Class I or II wells, incinerated, or released to waters only after treatment by a POTW or WWT with biological treatment (40 CFR 721.90 a(2)(ii), b(2)(ii), c(2)(ii)). Recommended testing will include the Cripes test that was previously going to be required.

Part IV: Risk Summary

A. Health Effects:

Absorption is nil through the skin based on physical/chemical properties, poor through the GI tract based on

analogs, and moderate through the lungs based on analogs. There is concern for lung effects through [redacted] if respirable particles are inhaled and concern for irritation to all exposed tissues based on [redacted] There is also uncertain concern for developmental toxicity based on summary data provided in the submission for the analog, [redacted], which seemed to cause more effects in mice (litter loss at 300 mg/kg) than in other species. In repeated dose studies, the analogs included in the submission showed low toxicity with NOELs of about 200 mg/kg with non-specific effects such as reduced weight gain at higher doses. Low moderate concern.

B. Environmental Effects:

Ecotox: predicted (P) and measured (M) toxicity value is mg/L (ppm) are:

Fish 96-h LC50:	11(P)
Daphnid 48-h LC50:	2.4(P)
Green algal 96-h EC50:	5.6(P)
Fish Chronic Value:	1.7(P)
Daphnid ChV:	0.37(P)
Algal ChV:	0.95(P)

C. Environmental Releases and Exposures:

D. Risk Estimates:

Part V: Exposure Criteria Met

Exposure Based Review (Chemistry):	● Yes ○ No	**Exposure Based Review (Health):**	○ Yes ● No
Exposure Based Review (Ecotox):	● Yes ○ No	**Exposure Based Review (Occupational):**	● Yes ○ No
Exposure Based Review (Non-Occupational):	○ Yes ● No	**Exposure Based Review (Environmental):**	● Yes ○ No

Exposure Based Review Criteria--Engineering Report		Amt
2. > 100 Workers With > 10 mg/Day Inhalation Exposure	Yes	

Exposure Parameter	Exposure-Based	Persistent/Bioaccum	Exposure Value
Surface DW:	● Yes ○ No	● Yes ○ No	[redacted]
Water Releases:	● Yes ○ No	● Yes ○ No	[redacted]
Total Releases:	● Yes ○ No	● Yes ○ No	[redacted]

Part VI: Tests

Final Testing Recommendation

Health:
Eco: Fish acute toxicity test (OPPTS: 850.1075), Aquatic Invertebrate acute toxicity test freshwater daphid (OPPTS:
Fate:
Other:

Comments:

Part VII: Other Factors

A. Substitutes:

B. Benefits:

C. Other Uses: Analog [redacted] t [redacted]. Analog [redacted]

D. Other:

Part VIII: Regulatory History

[redacted] PENDING 5(e)C ORDER DEVELOPMENT EXPOSURE-BASED

Comments:

Last Updated by

Document Created by Kristan Markey **on** 11/17/2011

[redacted]

[redacted]

February 14, 2013

Mr. Kristan Markey
The Program Manager
US Environmental Protection Agency,
EPA East Building, Room 4133G
1201 Constitution Avenue, NW
Washington, DC 20004

CONTAINS NO CBI
2/19/2013
JM 3/1/2013

RE: PMNs P-09-0447 and P-08-0448

Dear Mr. Markey,

Please find enclosed one singed copy of the Consent Order for the above referenced premanufacture notices (PMNs).
If you have any questions please feel free to contact me a [redacted] or [redacted]

[redacted]

CONTAINS NO CBI 3/1/2013

JM 3/1/2013

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

OFFICE OF POLLUTION PREVENTION AND TOXICS

REGULATION OF A NEW CHEMICAL SUBSTANCE

PENDING DEVELOPMENT OF INFORMATION

In the matter of:	)	Premanufacture Notice Numbers:
	)	
	)	
	)	
	)	
	)	
[redacted]	)	P-09-0447 and P-09-0448
	)	
	)	
	)	
	)	
	)	

Consent Order and Determinations Supporting Consent Order

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

OFFICE OF POLLUTION PREVENTION AND TOXICS

REGULATION OF A NEW CHEMICAL SUBSTANCE

PENDING DEVELOPMENT OF INFORMATION

In the matter of:	)	Premanufacture Notice Numbers:
	)	
	)	
	)	
	)	
	)	
[redacted]	)	P-09-0447 and P-09-0448
	)	
	)	
	)	
	)	
	)	

Consent Order and Determinations Supporting Consent Order

TABLE OF CONTENTS

PREAMBLE

I. INTRODUCTION

Under the authority of § 5(e) of the Toxic Substances Control Act ("TSCA") (15 U.S.C. 2604(e)), the Environmental Protection Agency ("EPA" or "the Agency") issues the attached Order, regarding premanufacture notices ("PMN") P-09-0447 and P-09-0448 for the chemical substances [redacted] ("the PMN substances") submitted by [redacted] ("the Company"), to take effect upon expiration of the PMN review period. The Company submitted the PMNs to EPA pursuant to § 5(a)(1) of TSCA and 40 CFR Part 720.

Under § 15 of TSCA, it is unlawful for any person to fail or refuse to comply with any provision of § 5 or any order issued under § 5. Violators may be subject to various penalties and to both criminal and civil liability pursuant to § 16, and to specific enforcement and seizure pursuant to § 17. In addition, chemical substances subject to an Order issued under § 5 of TSCA, such as this one, are subject to the § 12(b) export notice requirement.

II. SUMMARY OF TERMS OF THE ORDER

The Consent Order for these PMN substances requires the Company to:

(a) label the PMN substances and provide Material Safety Data Sheets ("MSDS") and worker training in accordance with the provisions of the Hazard Communication Program section;

(b) not use the PMN substances other than as [redacted] enhanced oil recovery applications

(c) distribute the PMN substances only to a person who agrees to follow the same restrictions and to not further distribute the PMN substances until it has been partitioned into oil or petroleum streams following use as [redacted] enhanced oil recovery applications;

(d) comply with the Release to Water provisions; and

(e) maintain certain records.

III. CONTENTS OF PMN

By signing this Order, the Company represents that it has carefully reviewed this document and agrees that all information herein that is claimed as confidential by the Company is correctly identified within brackets and that any information that is not bracketed is not claimed as confidential. To make this document available for public viewing, EPA will remove only the information contained within the brackets.

Confidential Business Information Claims (Bracketed in the Preamble and Order):

Chemical identity, Company Name, Production Volume, Uses, Processing information

Chemical Identity:

Premanufacture Number	Specific Chemical Identity	Generic Chemical Identity
P-09-0447	[redacted]	Sodium olefin sulfate derivative
P-08-0448	[redacted]	Sodium olefin sulfate derivative

Use:

Premanufacture Number	Specific Use	Generic Use	Maximum 12-month production volume
P-09-0447	[redacted] enhanced oil recovery applications	Enhanced oil recovery applications	[redacted]
P-08-0448	[redacted] enhanced oil recovery applications	Enhanced oil recovery applications	[redacted]

Test Data Submitted with the PMNs:

- The Company developed a base set of acute ecotoxicity data (fish, daphnia, algae) on a related case [redacted] that was accepted for read-across data on P-09-0447 and P-09-448.

IV. EPA'S ASSESSMENT OF RISK

The following are EPA's predictions regarding the probable toxicity and environmental releases of the PMN substances, based on the information currently available to the Agency.

Environmental Effects Summary:

See www.epa.gov/opptintr/newchems/pubs/chemcat.htm

Property	P-09-0447	P-09-0448
Regulatory and toxicological chemical class	Anionic surfactants	Anionic surfactants
Chronic Concern	10 ppb	10 parts per

Concentration (parts per billion ("ppb"))		billion ("ppb")
Acute Concern Concentration (ppb)	200 ppb	200 ppb

P-09-0447 and P-09-0448:

Based on QSAR information for similar anionic surfactants, EPA originally predicted a chronic concern concentration at 37 ppb. The Company requested that EPA review acute ecological toxicity data from another case, [redacted] to ascertain whether the data could be used in a read-across fashion. EPA agreed that the acute aquatic test data from [redacted] could substitute for the need for acute aquatic toxicity testing for P-09-0447 and P-09-0448. They are structurally and ecotoxicologically reasonable analogs for each other. Based on analog data from [redacted], the updated acute concentration of concern is 200 ppb. The updated chronic concentration of concern for P-09-447/448 changed from 37 ppb (predicted) to 10 ppb (based on analog measured data).

Environmental Release Summary:

During the initial review of the PMNs that applied generic engineering scenarios published by EPA relevant to the notified use, EPA assessed the following releases and exposures of the PMN substances.

	Manufacture	Processing/Use
# Sites	[ ]	[ ]
Workers (#/site)	[ ]	[ ]
Exposure (days/year)	[ ]	[ ]
Dermal Exposure (mg/day)	[ ]	[ ]
Inhalation Exposure (mg/day)	[ ]	[ ]
Drinking Water Exposure (mg/day)	[ ] acute [ ] chronic	[ ] acute [ ] chronic
Releases (days/year)	[ ]	[ ]
Release to Water (kg/day)	[ ]	[ ]
Surface Water Concentration (ppb)	Up to [ ]	Up to [ ]
Days Exceeding Concern Level	50	35

As part of this Consent Order, the Company has agreed to limit any predictable or purposeful release of the PMN substances, or any waste stream from manufacturing, processing, and use containing the PMN substances, into the waters of the United States that would result in surface water concentrations exceeding 10 part per billion ("ppb"), when calculated using the methods

described in 40 CFR 721.91. Except for quantities of the PMN substances that have partitioned into oil or petroleum streams following use as [redacted] enhanced oil recovery applications, the Company shall distribute the PMN substances outside the Company only to a person who has agreed in writing prior to the date of distribution, to, among other requirements, to also abide by this water release trigger and shall maintain such agreements on file for inspection by the Agency.

V. EPA'S CONCLUSIONS OF LAW

The following findings constitute the basis of the Consent Order:

(a) EPA is unable to determine the potential for ecological toxicity and environmental fate from environmental release of the PMN substances. EPA therefore concludes, pursuant to § 5(e)(1)(A)(i) of TSCA, that the information available to the Agency is insufficient to permit a reasoned evaluation of the environmental effects of the PMN substances.

(b) In light of the potential risk of ecological toxicity posed by the uncontrolled manufacture, import, processing, distribution in commerce, use, and disposal of the PMN substances, EPA has concluded, pursuant to § 5(e)(1)(A)(ii)(I) of TSCA, that uncontrolled manufacture, import, processing, distribution in commerce, use, and disposal of the PMN substances may present an unreasonable risk of injury to the environment.

VI. INFORMATION REQUIRED TO EVALUATE ENVIRONMENTAL EFFECTS

Pended Testing. The following additional information would be required to evaluate the following effects which may be caused by the PMN substances:

Information	Effects	Guideline
Fish early life stage test	Ecotoxicity – releases to the environment	OPPTS 850.1300
Daphnid chronic toxicity test	Ecotoxicity – releases to the environment	OPPTS 850.1400

The testing may be conducted on either P-09-0447 or P-09-0448. The Order does not require submission of the above pended testing at any specified time or production volume. However, the Order's restrictions on manufacture, import, processing, distribution in commerce, use, and disposal of the PMN substances will remain in effect until the Order is modified or revoked by EPA based on submission of that or other relevant information.

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

JAN 3 1 2013

CONSENT ORDER

(a) Scope. The requirements of this Order apply to all commercial manufacturing, processing, distribution in commerce, use and disposal of the chemical substances P:09-0447: [redacted] and; P-09-0448: [redacted] ("the PMN substances") in the United States by the [redacted] ("the Company"), except to the extent that those activities are exempted by paragraph (b).

(b) Exemptions. Manufacturing, processing, distribution in commerce, use and disposal of the PMN substances are exempt from the requirements of this Order (except the requirements in the Recordkeeping and Successor Liability Upon Transfer Of Consent Order sections) only to the extent that (1) these activities are conducted in full compliance with all applicable requirements of

the following exemptions, and (2) such compliance is documented by appropriate recordkeeping as required in the Recordkeeping section of this Order.

(1) Export. Until the Company begins commercial manufacture of the PMN substances for use in the United States, the requirements of this Order do not apply to manufacture, processing or distribution in commerce of the PMN substances solely for export in accordance with TSCA §§12(a) and 12(b), 40 CFR 720.3(s) and 40 CFR Part 707. However, once the Company begins to manufacture the PMN substances for use in the United States, no further activity by the Company involving the PMN substances are exempt as "solely for export" even if some amount of the PMN substances are later exported. At that point, the requirements of this Order apply to all activities associated with the PMN substances while in the territory of the United States. Prior to leaving U.S. territory, even those quantities or batches of the PMN substances that are destined for export are subject to terms of the Order, and count towards any production volume test triggers in the Testing section of this Order.

(2) Research & Development ("R&D"). The requirements of this Order do not apply to manufacturing, processing, distribution in commerce, use and disposal of the PMN substances in small quantities solely for research and development in accordance with TSCA §5(h)(3), 40 CFR 720.3(cc), and 40 CFR 720.36. The requirements of this Order also do not apply to manufacturing, processing, distribution in commerce, use and disposal of the PMN substances when manufactured solely for non-commercial research and development per TSCA §5(i) and 40 CFR 720.30(i).

(3) Byproducts. The requirements of this Order do not apply to the PMN substances when it is produced, without separate commercial intent, only as a "byproduct" as defined at 40 CFR 720.3(d) and in compliance with 40 CFR 720.30(g).

(4) No Separate Commercial Purpose. The requirements of this Order do not apply to the PMN substances when it is manufactured, pursuant to any of the exemptions in 40 CFR 720.30(h), with no commercial purpose separate from the substance, mixture, or article of which it is a part.

(5) Imported Articles. The requirements of this Order do not apply to the PMN substances when it is imported as part of an "article" as defined at 40 CFR 720.3(c) and in compliance with 40 CFR 720.22(b)(1).

(6) Partitioned. The requirements of this Order do not apply to quantities of the PMN substances that have partitioned into oil or petroleum streams following use as [redacted] enhanced oil recovery applications.

(c) Automatic Sunset. If the Company has obtained for the PMN substances a Test Market Exemption ("TME") under TSCA §5(h)(1) and 40 CFR 720.38 or a Low Volume Exemption ("LVE") or Low Release and Exposure Exemption ("LoREX") under TSCA §5(h)(4) and 40 CFR 723.50(c)(1) and (2) respectively, any such exemption is automatically rendered null and void as of the effective date of this Consent Order.

II. TERMS OF MANUFACTURE, IMPORT, PROCESSING, DISTRIBUTION IN COMMERCE, USE, AND DISPOSAL PENDING SUBMISSION AND EVALUATION OF INFORMATION

PROHIBITION

The Company is prohibited from manufacturing, importing, processing, distributing in commerce, using, or disposing of the PMN substances in the United States, for any nonexempt commercial purpose, pending the development of information necessary for a reasoned evaluation of the environmental effects of the substance, and the completion of EPA's review of, and regulatory action based on, that information, except in accordance with the conditions described in this Order.

TESTING

(a) Section 8(e) Reporting. Reports of information on the PMN substances which reasonably supports the conclusion that the PMN substances presents a substantial risk of injury to health or the environment and which is required to be reported under TSCA section 8(e) shall reference the appropriate PMN identification number for this substance and contain a statement that the substance is subject to this Consent Order. Additional information regarding section 8(e) reporting requirements can be found at www.epa.gov/oppt/tsca8e.

(b) Notice of Study Scheduling. The Company shall notify, in writing, the EPA Monitoring Assistance and Media Programs Division (2227A), Office of Enforcement and Compliance Assurance, U.S. Environmental Protection Agency, 1200 Pennsylvania Avenue, N.W.,

Washington, D.C. 20460, of the following information within 10 days of scheduling any study required to be performed pursuant to this Order, or within 15 days after the effective date of this Order, whichever is later:

(1) The date when the study is scheduled to commence;

(2) The name and address of the laboratory which will conduct the study;

(3) The name and telephone number of a person at the Company or the laboratory whom EPA may contact regarding the study; and,

(4) The appropriate PMN identification number for each substance and a statement that the substance is subject to this Consent Order.

(c) Good Laboratory Practice Standards and Test Protocols. Each study performed to address the risks identified in this Order must be conducted according to TSCA Good Laboratory Practice Standards at 40 CFR Part 792 and using methodologies generally accepted in the relevant scientific community at the time the study is initiated. Before starting to conduct any study that will use a modified version of a published test guideline, the Company must submit written test protocols to EPA for review (submission of written test protocols is optional for tests that are to be conducted using unmodified published test guidelines). Protocols must be submitted as a support document for the PMN, using the procedures set out in 40 CFR 720.40 [if for order is for SNUN, add "and 721.25"]. EPA will respond to the Company within 4 weeks of receiving the written protocols. EPA review of a test protocol does not mean pre-acceptance of test results.

(d) Unreasonable Risk. EPA may notify the Company in writing that EPA finds that the data generated by a study are scientifically valid and unequivocal and indicate that, despite the terms of this Order, the PMN substances will or may present an unreasonable risk of injury to human health or the environment. EPA's notice may specify that the Company undertake certain actions concerning further testing, manufacture, import, processing, distribution, use and/or disposal of the PMN substances to mitigate exposures to or to better characterize the risks presented by the PMN substances. Within 2 weeks from receipt of such a notice, the Company must cease all manufacture, import, processing, distribution, use and disposal of the PMN substance, unless either:

(1) within 2 weeks from receipt of the EPA notice, the Company complies with such requirements as the notice specifies; or

(2) within 4 weeks from receipt of the EPA notice, the Company submits to EPA a written report refuting EPA's finding and/or the appropriateness of any additional requirements imposed by EPA. The Company may continue to manufacture, import, process, distribute, use and dispose of the PMN substances in accordance with the terms of this Order pending EPA's response to the Company's written report. EPA will respond to the Company, in writing, within 4 weeks of receiving the Company's report. Within 2 weeks of receipt of EPA's written response, the Company shall comply with any requirements imposed by EPA's response or cease all manufacture, import, processing, distribution, use and disposal of the PMN substance.

(e) Other Requirements. Regardless of the satisfaction of any other conditions in this Testing section, the Company must continue to obey all the terms of this Consent Order until otherwise

notified in writing by EPA. The Company may, based upon submitted test data or other relevant information, petition EPA to modify or revoke provisions of this Consent Order pursuant to Part VI. of this Consent Order.

HAZARD COMMUNICATION PROGRAM

(a) Written Hazard Communication Program. The Company shall develop and implement a written hazard communication program for the PMN substances in each workplace. The written program will, at a minimum, describe how the requirements of this section for labels, MSDSs, and other forms of warning material will be satisfied. The Company must make the written hazard communication program available, upon request, to all employees, contractor employees, and their designated representatives. The Company may rely on an existing hazard communication program, including an existing program established under the OSHA Hazard Communication Standard (29 CFR 1910.1200), to comply with this paragraph provided that the existing hazard communication program satisfies the requirements of this section. The written program shall include the following:

(1) A list of chemical substances known to be present in the work area which are subject to a TSCA section 5(e) consent order signed by the Company or to a TSCA section 5(a)(2) SNUR at 40 CFR Part 721, subpart E. The list must be maintained in each work area where the PMN substances are known to be present and must use the identity provided on the MSDS for the substance required under paragraph (c) of this section. The list may be compiled for the workplace or for individual work areas. If the Company is required either by another Order issued under

section 5(e) of TSCA, or by a TSCA section 5(a)(2) SNUR at 40 CFR Part 721, subpart E, to maintain a list of substances, the lists shall be combined with the list under this subparagraph.

(2) The methods the Company will use to inform employees of the hazards of non-routine tasks involving the PMN substances (e.g., cleaning of reactor vessels), and the hazards associated with the PMN substances contained in unlabeled pipes in their work area.

(3) The methods the Company will use to inform contractors of the presence of the PMN substances in the Company's workplace and of the provisions of this Order if employees of the contractor work in the Company's workplace and are reasonably likely to be exposed to the PMN substances while in the Company's workplace.

(b) Labeling.

(1) The Company shall ensure that each container of the substance in the workplace is labeled in accordance with this subparagraph (b)(1).

(i) The label shall, at a minimum, contain the following information:

(A) A statement of the health hazards(s) and precautionary measure(s), if any, identified either in paragraph (f) of this section or by the Company, for the PMN substance.

(B) The identity by which the PMN substances may be commonly recognized.

(C) A statement of the environmental hazard(s) and precautionary measure(s), if any, identified either in paragraph (f) of this section, or by the Company, for the PMN substance.

(D) A statement of exposure and precautionary measure(s), if any, identified either in paragraph (f) of this section, or by the Company, for the PMN substance.

(ii) The Company may use signs, placards, process sheets, batch tickets, operating procedures, or other such written materials in lieu of affixing labels to individual stationary process containers, as long as the alternative method identifies the containers to which it is applicable and conveys information specified by subparagraph (b)(1)(i) of this section. Any written materials must be readily accessible to the employees in their work areas throughout each work shift.

(iii) The Company need not label portable containers into which the PMN substances are transferred from labeled containers, and which are intended only for the immediate use of the employee who performs the transfer.

(iv) The Company shall not remove or deface an existing label on containers of the PMN substances obtained from persons outside the Company unless the container is immediately re-labeled with the information specified in subparagraph (b)(1)(i) of this section.

(2) The Company shall ensure that each container of the substance leaving its workplace for distribution in commerce is labeled in accordance with this subparagraph (b)(2).

(i) The label shall, at a minimum, contain the following information:

(A) The information prescribed in subparagraph (b)(1)(i) of this section.

(B) The name and address of the manufacturer or a responsible party who can provide additional information on the substance for hazard evaluation and any appropriate emergency procedures.

(ii) The label shall not conflict with the requirements of the Hazardous Materials Transportation Act (18 U.S.C. 1801 et. seq.) and regulations issued under that Act by the Department of Transportation.

(3) The label, or alternative forms of warning, shall be legible and prominently displayed.

(4) The label, or alternative forms of warning, shall be printed in English; however, the information may be repeated in other languages.

(5) If the label or alternative form of warning is to be applied to a mixture containing the PMN substances in combination with any other substance that is either subject to another TSCA section 5(e) Order applicable to the Company, or subject to a TSCA section 5(a)(2) SNUR at 40 CFR Part 721, subpart E, or defined as a "hazardous chemical" under the OSHA Hazard Communication Standard (29 CFR 1900.1200), the Company may prescribe on the label, MSDS, or alternative form of warning, the measures to control worker exposure or environmental release which the Company determines provide the greatest degree of protection. However, should these control measures differ from the applicable measures required under this Order, the Company must seek a determination of equivalency for such alternative control measures pursuant to 40 CFR 721.30 before prescribing them under this subparagraph (b)(5).

(6) If the Company becomes aware of any significant new information regarding the hazards of the PMN substances or ways to protect against the hazards, this new information must be added to the label within 3 months from the time the Company becomes aware of the new information. If the PMN substances are not being manufactured, imported, processed, or used in the Company's workplace, the Company must add the new information to the label before the PMN substances are reintroduced into the workplace.

(c) Material Safety Data Sheets.

(1) The Company must obtain or develop an MSDS for the PMN substance.

(2) The MSDS shall contain, at a minimum, the following information:

(i) The identity used on the container label of the PMN substances under this section, and, if not claimed confidential, the chemical and common name of the PMN substance. If the chemical and common names are claimed confidential, generic chemical names must be used.

(ii) Physical and chemical characteristics of the substance known to the Company, (e.g., vapor pressure, flash point).

(iii) The physical hazards of the substance known to the Company, including the potential for fire, explosion, and reactivity.

(iv) The potential human and environmental hazards as specified in paragraph (f) of this section.

(v) Signs and symptoms of exposure, and any medical conditions which are expected to be aggravated by exposure to the PMN substances known to the Company.

(vi) The primary routes of exposure to the PMN substance.

(vii) Precautionary measures to control worker exposure and/or environmental release required by this Order, or alternative control measures which EPA has determined under 40 CFR 721.30 provide substantially the same degree of protection as the identified control measures.

(viii) Any generally applicable precautions for safe handling and use of the PMN substances which are known to the Company, including appropriate hygienic practices, protective

measures during repair and maintenance of contaminated equipment, and procedures for response to spills and leaks.

(ix) Any generally applicable control measures which are known to the Company, such as appropriate engineering controls, work practices, or personal protective equipment.

(x) Emergency first aid procedures known to the Company.

(xi) The date of preparation of the MSDS or of its last revision.

(xii) The name, address, and telephone number of the Company or another responsible party who can provide additional information on the chemical substance and any appropriate emergency procedures.

(3) If no relevant information is found or known for any given category on the MSDS, the Company must mark the MSDS to indicate that no applicable information was found.

(4) Where multiple mixtures containing the PMN substances have similar compositions (i.e., the chemical ingredients are essentially the same, but the specific composition varies from mixture to mixture) and similar hazards, the Company may prepare one MSDS to apply to all of these multiple mixtures.

(5) If the Company becomes aware of any significant new information regarding the hazards of the PMN substances or ways to protect against the hazards, this new information must be added to the MSDS within 3 months from the time the Company becomes aware of the new information. If the PMN substances are not being manufactured, imported, processed, or used in the Company's workplace, the Company must add the new information to the MSDS before the PMN substances are reintroduced into the workplace.

(6) The Company must ensure that persons receiving the PMN substances from the Company are provided an appropriate MSDS with their initial shipment and with the first shipment after an MSDS is revised. The Company may either provide the MSDS with the shipped containers or send it to the person prior to or at the time of shipment.

(7) The Company must maintain a copy of the MSDS in its workplace, and must ensure that it is readily accessible during each work shift to employees when they are in their work areas.

(8) The MSDS may be kept in any form, including as operating procedures, and may be designed to cover groups of substances in a work area where it may be more appropriate to address the potential hazards of a process rather than individual substances. However, in all cases, the required information must be provided for the PMN substances and must be readily accessible during each work shift to employees when they are in their work areas.

(9) The MSDS must be printed in English; however, the information may be repeated in other languages.

(d) Employee Information and Training. The Company must ensure that employees are provided with information and training on the PMN substance. This information and training must be provided at the time of each employee's initial assignment to a work area containing the PMN substances and whenever the PMN substances are introduced into the employee's work area for the first time.

(1) The information provided to employees under this paragraph shall include:

(i) The requirements of this section.

(ii) Any operations in the work area where the PMN substances are present.

(iii) The location and availability of the written hazard communication program required under paragraph (a) of this section, including the list of substances required by subparagraph (a)(1) of this section and MSDSs required by paragraph (c) of this section.

(2) The training provided to employees shall include:

(i) Methods and observations that may be used to detect the presence or release of the PMN substances in or from an employee's work area (such as exposure monitoring conducted by the Company, continuous monitoring devices, visual appearance, or odor of the substances when being released).

(ii) The potential human health and environmental hazards of the PMN substances as specified in paragraph (f) of this section.

(iii) The measures employees can take to protect themselves and the environment from the PMN substances, including specific procedures the Company has implemented to protect employees and the environment from exposure to the PMN substance, including appropriate work practices, emergency procedures, personal protective equipment, engineering controls, and other measures to control worker exposure and/or environmental release required under this Order, or alternative control measures which EPA has determined under 40 CFR 721.30 provide the same degree of protection as the specified control measures.

(iv) The requirements of the hazard communication program developed by the Company under this section, including an explanation of the labeling system and the MSDS required by this section and guidance on obtaining and using appropriate hazard information.

(e) De Minimis Concentrations. The requirements of this Hazard Communication section do not apply to quantities of the PMN substances that are (1) present in the work area only as a mixture and (2) at a concentration not to exceed 1.0 percent by weight or volume (0.1 percent by weight or volume if the PMN substances are identified as a potential carcinogen in paragraph (f) of the Hazard Communication Program section of this Order). This exemption is not available if the Company has reason to believe that, during intended activities, the PMN substances in the mixture may be reconcentrated above the 1.0 or 0.1 percent level, whichever applies. If this Order contains New Chemical Exposure Limits provisions or Release to Water provisions that, respectively, specify a NCEL concentration ("TWA") or in-stream concentration ("N") less than the de minimis concentration specified here, then this de minimis exemption does not apply to those provisions.

(f) Human Health, Environmental Hazard, Exposure, and Precautionary Statements. The following human health and environmental hazard and precautionary statements shall appear on each label as specified in paragraph (b) and the MSDS as specified in paragraph (c) of this section:

(1) Environmental hazard statements. These substances may be:

(i) toxic to fish.

(ii) toxic to aquatic organisms.

(2) Environmental hazard precautionary statements. Notice to users:

(i) disposal restrictions apply.

(3) The environmental hazard and precautionary statement on the label prepared pursuant to paragraph (b) of this section must be followed by the statement: "See the MSDS for details."

MANUFACTURING

(a)(1) Prohibition. The Company shall not cause, encourage, or suggest the manufacture or import of the PMN substances by any other person.

(2) Sunset Following SNUR. Subparagraph (a)(1) shall expire 75 days after promulgation of a final significant new use rule ("SNUR") governing the PMN substances under section 5(a)(2) of TSCA unless the Company is notified on or before that day of an action in a Federal Court seeking judicial review of the SNUR. If the Company is so notified, subparagraph (a)(1) shall not expire until EPA notifies the Company in writing that all Federal Court actions involving the SNUR have been resolved and the validity of the SNUR affirmed.

(3) Notice of SNUR. When EPA promulgates a final SNUR for the PMN substances and subparagraph (a)(1) expires in accordance with subparagraph (a)(2), the Company shall notify each person whom it causes, encourages or suggests to manufacture or import the PMN substances of the existence of the SNUR.

USE

(a) The Company shall not use the PMN substances other than as described in the PMNs.

DISTRIBUTION

(a) Export Notice Requirement. No later than the date of distribution, the Company shall notify in writing any person to whom it distributes the PMN substances that, due to the issuance of this Consent Order under section 5(e) of TSCA, the PMN substances are subject to the export notification requirements of TSCA section 12(b) and 40 CFR Part 707 Subpart D. Such notice

shall contain, in the form in which it appears in this Consent Order, the following information: (1) the PMN number, and (2) either (A) the specific chemical identity of the PMN substances, or (B) if the specific chemical identity is confidential, the generic chemical identity.

(b) Distribution Requirements. (i) Except for quantities of the PMN substances that have partitioned into oil or petroleum streams following use as [redacted] enhanced oil recovery applications or as provided in paragraph (c), the Company shall distribute the PMN substances outside the Company only to a person who has agreed in writing prior to the date of distribution, to:

(1) Notify in writing any person to whom it distributes the PMN substances that, due to the issuance of this Consent Order under section 5(e) of TSCA, the PMN substances are subject to the export notification requirements of TSCA section 12(b) and 40 CFR Part 707 Subpart D. Such notice shall contain, in the form in which it appears in this Consent Order, the following information: (1) the PMN number, and (2) either (A) the specific chemical identity of the PMN substances, or (B) if the specific chemical identity is confidential, the generic chemical identity.

(2) Not further distribute the PMN substances to any other person, other than for disposal, except for quantities of the PMN substances that have partitioned into oil or petroleum streams following use as [redacted] enhanced oil recovery applications.

(3) Comply with the same requirements and restrictions, if any, required of the Company in the Hazard Communication Program section of this Order.

(4) Comply with the same environmental release restrictions, if any, required of the Company in the Disposal and Release to Water sections of this Order.

(5) Not use the PMN substances other than as described in the PMNs;

(c) Temporary Transport and Storage. Notwithstanding paragraph (b), the Company may distribute the PMN substances outside the Company for temporary transport and storage in "sealed containers" (defined for the purposes of this Order to exclude tank trucks, tractor trailers, train cars or other delivery vehicles with attached tanks) provided the following three conditions are met:

(1) Subsequent to any such exempt temporary transport or storage of sealed containers, the PMN substances may be distributed only to the Company or a person who has given the Company the written agreement required by paragraph (b).

(2) Any human exposure or environmental release resulting from opening the sealed containers and removing or washing out the PMN substances may occur only while the PMN substances are in the possession and control of the Company or a person who has given the Company the written agreement required by paragraph (b).

(3) The sealed containers must be labeled in accordance with paragraph (b)(2) of the Hazard Communication Program section of this Order.

(d) Recipient Non-Compliance.

(1) If, at any time after commencing distribution in commerce of the PMN substance, the Company obtains knowledge that a recipient or transporter of the substance has failed to comply with any of the conditions specified in paragraph (b) of this Distribution section or, after subparagraph (b)(2) expires in accordance with subparagraph (e)(1), has engaged in a significant

new use of the PMN substances (as defined in 40 CFR Part 721, Subpart E) without submitting a significant new use notice to EPA, the Company shall cease supplying the substance to that recipient, unless the Company is able to document each of the following:

(a) That the Company has, within 5 working days, notified the recipient in writing that the recipient has failed to comply with any of the conditions specified in paragraph (b) of this Distribution section, or has engaged in a significant new use of the PMN substances without submitting significant new use notices to EPA.

(b) That, within 15 working days of notifying the recipient of the noncompliance, the Company received from the recipient, in writing, a statement of assurance that the recipient is aware of the terms of paragraph (b) of this Distribution section and will comply with those terms, or is aware of the terms of the significant new use rules for the PMN substances and will not engage in significant new uses without submitting significant new use notices to EPA.

(c) If, after receiving a statement of assurance from a recipient under subparagraph (d)(1)(b) of this Distribution section, the Company obtains knowledge that the recipient has failed to comply with any of the conditions specified in paragraph (b) of this Distribution section, or has engaged in a significant new uses of the PMN substances without submitting a significant new use notice to EPA, the Company shall cease supplying the PMN substances to that recipient, shall notify EPA of the failure to comply, and shall resume supplying the PMN substances to that recipient only upon written notification from the Agency.

(2) If, at any time after commencing distribution in commerce of the PMN substance, EPA obtains knowledge (such as through a TSCA Section 11 inspection or subpoena), that a recipient of the substance has failed to comply with any of the conditions specified in

paragraph (b) of the Distribution section or, after subparagraph (b)(2) expires in accordance with subparagraph (e)(1), has engaged in a significant new use of the PMN substances (as defined in 40 CFR Part 721, Subpart E) without submitting a significant new use notice to EPA, EPA may notify the Company in writing that, despite the terms of this Order, EPA finds that the distribution in commerce of the PMN substances will or may present an unreasonable risk of injury to human health or the environment. EPA's notice may specify that the Company undertake certain actions concerning further testing, manufacture, import, processing, distribution, use and/or disposal of the PMN substances to mitigate exposures to better characterize the risks presented by the PMN substances. Within 2 weeks from receipt of such a notice, the Company must cease all manufacture, import, processing, distribution, use and disposal of the PMN substance, unless either:

(a) within 2 weeks from receipt of the EPA notice, the Company complies with such requirements as the notice specifies; or

(b) within 4 weeks from receipt of the EPA notice, the Company submits to EPA a written report refuting EPA's finding and/or the appropriateness of any additional actions imposed by EPA. The EPA will respond to the Company, in writing, within 4 weeks of receiving the Company's report. Within 2 weeks of receipt of EPA's written response, the Company shall comply with any requirements imposed by EPA's notice or revised response or, cease all manufacture, import, processing, distribution, use and disposal of the PMN substance.

(e) Sunset Following SNUR. (1) Subparagraphs (b)(2) and (d)(2) of this Distribution section shall expire 75 days after promulgation of a final SNURs for the PMN substances under section 5(a)(2) of TSCA, unless the Company is notified on or before that day of an action in a Federal Court seeking judicial review of the SNUR. If the Company is so notified, subparagraph (b)(2) and (d)(2) of this Distribution section shall not expire until EPA notifies the Company in writing that all Federal Court actions involving the SNUR have been resolved and the validity of the SNUR affirmed.

(2) When EPA promulgates a final SNUR for the PMN substances and subparagraphs (b)(2) and (d)(2) of this Distribution section expires in accordance with subparagraph (e)(1), the Company shall notify each person to whom it distributes the PMN substances of the existence of the SNURs. Such notification must be in writing and must specifically include all limitations contained in the SNURs which are defined as significant new uses, and which would invoke significant new use notification to EPA for the PMN substances. Such notice must also reference the publication of the SNURs for this PMN substances in either the Federal Register or the Code of Federal Regulations. After promulgation of SNURs and expiration of subparagraphs (b)(2) and (d)(2), such notices may substitute for the written agreements required in the introductory clause of paragraph (b); so that, if the Company provides such notices to the persons to whom it distributes the PMN substances, then the Company is not required to obtain from such persons the written agreements specified in paragraph (b).

RELEASE TO WATER

This provision does not supersede or preempt any applicable federal, state, and local laws and regulations. (Those other laws may be more stringent than the requirements below.) The Company is prohibited from any predictable or purposeful release of the PMN substances, or any waste stream from manufacturing, processing, and use containing the PMN substances:

(1)(a) Into the waters of the United States if the quotient from the formula:

$$\frac{\text{number of kilograms/day/site released}}{\text{receiving stream flow (million liters/day)}} \times 1000 = \text{N parts per billion}$$

exceeds 10 part per billion ("ppb") in aggregate, when calculated using the methods described in 40 CFR 721.91. However, 40 CFR 721.91(a)(4) does not apply. Instead, if the waste stream containing the PMN substances will be treated using biological treatment (activated sludge or equivalent) plus clarification, then the amount of PMN substances reasonably likely to be removed from the waste stream by such treatment may be subtracted in calculating the number of kilograms released. No more than 90 percent removal efficiency may be attributed to such treatment.

(b) In lieu of calculating the quotient in subparagraph (1)(a), monitoring or alternative calculations may be used to predict the surface water concentration expected to result from the intended release of the substance, if the monitoring procedures or calculations have been approved for such purpose by EPA. EPA will review and act on a written request to approve monitoring procedures or alternative calculations within 90 days after such a request is received. The Agency will inform the Company of the disposition of such requests in writing and, where a request is denied, will explain the reasons therefore.

III. RECORDKEEPING

(a) Records. The Company shall maintain the following records until 5 years after the date they are created and shall make them available for inspection and copying by EPA in accordance with section 11 of TSCA:

(1) Exemptions. Records documenting that the PMN substances did in fact qualify for any one or more of the exemptions described in Section I, Paragraph (b) of this Order. Such records must satisfy all the statutory and regulatory recordkeeping requirements applicable to the exemption being claimed by the Company. Any amounts or batches of the PMN substances eligible for the export only exemption in Section I, Paragraph (b)(1) of this Order are exempt from all the requirements in this Recordkeeping section, if the Company maintains, for 5 years from the date of their creation, copies of the export label and export notice to EPA, required by TSCA sections 12(a)(1)(B) and 12(b), respectively. Any amounts or batches of the PMN substances eligible for the research and development exemption in Section I, Paragraph (b)(2) of this Order are exempt from all the requirements in this Recordkeeping section, if the Company maintains, for 5 years from the date of their creation, the records required by 40 CFR 720.78(b). For any amounts or batches of the PMN substances claimed to be eligible for any other exemption described in Section I, Paragraph (b) of this Order, the Company shall keep records demonstrating qualification for that exemption as well as the records specified in paragraphs (2) and (3) below, but is exempt from the other recordkeeping requirements in this Recordkeeping section;

(2) Records documenting the manufacture and importation volume of the PMN substances and the corresponding dates of manufacture and import;

(3) Records documenting the names and addresses (including shipment destination address, if different) of all persons outside the site of manufacture or import to whom the Company directly sells or transfers the PMN substance, the date of each sale or transfer, and the quantity of the substance sold or transferred on such date;

(4) Records documenting the address of all sites of manufacture, import, processing, and use;

(5) Records documenting establishment and implementation of the hazard communication program required by the Hazard Communication Program section of this Order;

(6) Copies of labels required under the Hazard Communication Program section of this Order;

(7) Copies of Material Safety Data Sheets required by the Hazard Communication Program section of this Order;

(8) Records documenting compliance with any applicable manufacturing, processing, use, and distribution restrictions in the Manufacturing, Processing, Use, and Distribution sections of this Order, including distributees' written agreement to comply with the Distribution section of this Order;

(9) Records documenting compliance with any applicable disposal requirements under the Disposal section of this Order, including method of disposal, location of disposal sites, dates of disposal, and volume of PMN substances disposed. Where the estimated disposal volume is not known to the Company and is not reasonably ascertainable by the Company, the Company must

maintain other records which demonstrate establishment and implementation of a program that ensures compliance with any applicable disposal requirements;

(10) Records documenting establishment and implementation of procedures that ensure compliance with any applicable water discharge limitation in the Release to Water section of this Order;

(11) Copies of any Transfer Documents and notices required by the Successor Liability section of this Order, if applicable; and,

(12) The Company shall keep a copy of this Order at each of its sites where the PMN substances are manufactured or imported.

(b) Applicability. The provisions of this Recordkeeping Section are applicable only to activities of the Company and its Contract Manufacturer, if applicable, and not to activities of the Company's customers.

(c) OMB Control Number. Under the Paperwork Reduction Act and its regulations at 5 CFR Part 1320, particularly 5 CFR 1320.5(b), the Company is not required to respond to this "collection of information" unless this Order displays a currently valid control number from the Office of Management and Budget ("OMB"), and EPA so informs the Company. The "collection of information" required in this TSCA §5(e) Consent Order has been approved under currently valid **OMB Control Number 2070-0012.**

IV. REQUESTS FOR PRE-INSPECTION INFORMATION

(a) EPA's Request for Information. Pursuant to section 11 of TSCA and 40 CFR 720.122, EPA may occasionally conduct on-site compliance inspections of Company facilities and conveyances associated with the PMN substance. To facilitate such inspections, EPA personnel may contact the Company in advance to request information pertinent to the scheduling and conduct of such inspections. Such requests may be written or oral. The types of information that EPA may request include, but are not limited to, the following:

(1) Expected dates and times when the PMN substances will be in production within the subsequent 12 months;

(2) Current workshift schedules for workers who are involved in activities associated with the PMN substances and may reasonably be exposed to the PMN substances;

(3) Current job titles or categories for workers who are involved in activities associated with the PMN substances and may reasonably be exposed to the PMN substances;

(4) Existing exposure monitoring data for workers who are involved in activities associated with the PMN substances and may reasonably be exposed to the PMN substances;

(5) Records required by the Recordkeeping section of this Order; and/or,

(6) Any other information reasonably related to determining compliance with this Order or conducting an inspection for that purpose.

(b) Company's Response. The Company shall respond to such requests within a reasonable period of time, but in no event later than 30 days after receiving EPA's request. When requested in writing by EPA, the Company's response shall be in writing. To the extent the information is

known to or reasonably ascertainable by the Company at the time of the request, the Company's response shall demonstrate a good faith effort to provide reasonably accurate and detailed answers to all of EPA's requests.

(c) Confidential Business Information. Any Confidential Business Information ("CBI") that the Company submits to EPA pursuant to paragraph (b) shall be protected in accordance with §14 of TSCA and 40 CFR Part 2.

V. SUCCESSOR LIABILITY UPON TRANSFER OF CONSENT ORDER

(a) Scope. This section sets forth the procedures by which the Company's rights and obligations under this Order may be transferred when the Company transfers its interests in the PMN substances, including the right to manufacture the PMN substances, to another person outside the Company (the "Successor in Interest").

(b) Relation of Transfer Date to Notice of Commencement ("NOC").

(1) Before NOC. If the transfer from the Company to the Successor in Interest is effective before EPA receives a notice of commencement of manufacture or import ("NOC") for the PMN substances from the Company pursuant to 40 CFR 720.102, the Successor in Interest must submit new PMNs to EPA and comply fully with Section 5(a)(1) of TSCA and 40 CFR part 720 before commencing manufacture or import of the PMN substances.

(2) After NOC. If the transfer from the Company to the Successor in Interest is effective after EPA receives a NOC, the Successor in Interest shall comply with the terms of this Order and shall not be required to submit a new PMN to EPA.

(c) Definitions. The following definitions apply to this Successor Liability section of the Order:

(1) "Successor in Interest" means a person outside the Company who has acquired the Company's full interest in the rights to manufacture the PMN substances, including all ownership rights and legal liabilities, through transfer documents signed by the Company, as transferor, and the Successor in Interest, as transferee. The term excludes persons who acquire less than the full interest of the Company in the PMN substances, such as a licensee who has acquired a limited license to the patent or manufacturing rights associated with the PMN substances. A Successor in Interest must be incorporated, licensed, or doing business in the United States in accordance with 40 CFR 720.22(a)(3) and 40 CFR 720.3(z).

(2) "Transfer Document" means the legal instrument(s) used to convey the interests in the PMN substances, including the right to manufacture the PMN substances, from the Company to the Successor in Interest.

(d) Notices.

(1) Notice to Successor in Interest. On or before the effective date of the transfer, the Company shall provide to the Successor in Interest, by registered mail, a copy of the Consent Order and the "Notice of Transfer" document which is incorporated by reference as Attachment B to this Order.

(2) Notice to EPA. Within 10 business days of the effective date of the transfer, the Company shall, by registered mail, submit the fully executed Notice of Transfer document to: U.S. Environmental Protection Agency, New Chemicals Management Branch (7405), 1200 Pennsylvania Avenue, N.W., Washington, D.C. 20460.

(3) Transfer Document. Copies of the Transfer Document must be maintained by the Successor in Interest at its principal place of business, and at all sites where the PMN substances are manufactured or imported. Copies of the Transfer Document must also be made available for inspection pursuant to Section 11 of TSCA, must state the effective date of transfer, and must contain provisions which expressly transfer liability for the PMN substances under the terms of this Order from the Company to the Successor in Interest.

(c) Liability.

(1) The Company shall be liable for compliance with the requirements of this Order until the effective date of the transfer described above.

(2) The Successor in Interest shall be liable for compliance with the requirements of this Order effective as of the date of transfer.

(3) Nothing in this section shall be construed to prohibit the Agency from taking enforcement action against the Company after the effective date of the transfer for actions taken, or omissions made, during the time in which the Company manufactured, processed, used, distributed in commerce, or disposed of the PMN substances pursuant to the terms of this Consent Order.

VI. MODIFICATION AND REVOCATION OF CONSENT ORDER

(a) Petitions.

(1) The Company may petition EPA at any time, based upon new information on the environmental effects or environmental release of the PMN substances, to modify or revoke substantive provisions of this Order.

(2) The exposures and risks identified by EPA during its review of the PMN substances and the information EPA determined to be necessary to evaluate those exposures and risks are described in the preamble to this Order. However, in determining whether to amend or revoke this Order, EPA will consider all relevant information available at the time the Agency makes that determination, including, where appropriate, any reassessment of the test data or other information that supports the findings in this Order, an examination of new test data or other information or analysis, and any other relevant information.

(3) EPA will issue a modification or revocation if EPA determines that the activities proposed therein will not present an unreasonable risk of injury to health or the environment and will not result in significant or substantial human exposure or substantial environmental release in the absence of data sufficient to permit a reasoned evaluation of the health or environmental effects of the PMN substances.

(4) In addition, the Company may petition EPA at any time to make other modifications to the language of this Order. EPA will issue such a modification if EPA determines that the modification is useful, appropriate, and consistent with the structure and intent of this Order as issued.

(b) Modification or Revocation by EPA. Based on study results describing in the paragraph (d) of the Testing Section or if EPA becomes aware of information that the terms of the Consent Order are not being adhered to by downstream users as described in paragraph (d)(2) of the Distribution Section, EPA may modify or revoke this Consent Order by following procedures set out in these paragraphs.

VII. EFFECT OF CONSENT ORDER

(a) Waiver. By consenting to the entry of this Order, the Company waives its rights to file objections to this Order pursuant to section 5(e)(1)(C) of TSCA, to receive service of this Order no later than 45 days before the end of the review period pursuant to section 5(e)(1)(B) of TSCA, and to challenge the validity of this Order in any subsequent action. Consenting to the entry of this Order, and agreeing to be bound by its terms, do not constitute an admission by the Company as to the facts or conclusions underlying the Agency's determinations in this proceeding. This waiver does not affect any other rights that the Company may have under TSCA.

(b) CBI Brackets. By signing this Order, the Company represents that it has carefully reviewed this document and hereby agrees that all information herein that is claimed as confidential by the Company (per section 14 of TSCA, 40 CFR Part 720 Subpart E, and 40 CFR Part 2) is correctly identified within brackets and that any information that is not bracketed is not claimed as confidential. To make this document available for public viewing, EPA will remove only the information contained within the brackets.

31 Jan 2013
Date

Maria J. Doa, Director
Chemical Control Division
Office of Pollution Prevention and Toxics

14 Feb. 2013
Date

[redacted]
Name: [redacted]
Title:[redacted]
Company: [redacted]

ATTACHMENT A

DEFINITIONS

Note: The attached Order may not contain some of the terms defined below.

"Chemical name" means the scientific designation of a chemical substance in accordance with the nomenclature system developed by the Chemical Abstracts Service's rules of nomenclature, or a name which will clearly identify a chemical substance for the purpose of conducting a hazard evaluation.

"Company" means the person or persons subject to this Order.

"Common name" means any designation or identification such as code name, code number, trade name, brand name, or generic chemical name used to identify a chemical substance other than by its chemical name.

"Container" means any bag, barrel, bottle, box, can, cylinder, drum, reaction vessel, storage tank, or the like that contains a hazardous chemical. For purposes of this section, pipes or piping systems, and engines, fuel tanks, or other operating systems in a vehicle, are not considered to be containers.

"Contract Manufacturer" means a person, outside the Company, who is authorized to manufacture and import the PMN substances under the conditions specified in Part II. of this Consent Order and in the Consent Order for Contract Manufacturer.

"Identity" means any chemical or common name used to identify a chemical substance or a mixture containing that substance.

"Immediate use." A chemical substance is for the "immediate use" of a person if it is under the control of, and used only by, the person who transferred it from a labeled container and will only be used by that person within the work shift in which it is transferred from the labeled container.

"Manufacturing stream" means all reasonably anticipated transfer, flow, or disposal of a chemical substance, regardless of physical state or concentration, through all intended operations of manufacture, including the cleaning of equipment.

"MSDS" means material safety data sheet, the written listing of data for the chemical substance.

"Non-industrial use" means use other than at a facility where chemical substances or mixtures are manufactured, imported, or processed.

"PMN substances" means the chemical substances described in the Premanufacture notice submitted by the Company relevant to this Order.

"Process stream" means all reasonably anticipated transfer, flow, or disposal of a chemical substance, regardless of physical state or concentration, through all intended operations of processing, including the cleaning of equipment.

"Scientifically invalid" means any significant departure from the EPA-approved protocol or the Good Laboratory Practice Standards at 40 CFR Part 792 without prior or subsequent Agency approval that prevents a reasoned evaluation of the health or environmental effects of the PMN substances.

"Scientifically equivocal data" means data which, although developed in apparent conformity with the Good Laboratory Practice Standards and EPA-approved protocols, are inconclusive, internally inconsistent, or otherwise insufficient to permit a reasoned evaluation of the potential risk of injury to human health or the environment of the PMN substances.

"Sealed container" means a closed container that is physically and chemically suitable for long-term containment of the PMN substances, and from which there will be no human exposure to, nor environmental release of, the PMN substances during transport and storage.

"Use stream" means all reasonably anticipated transfer, flow, or disposal of a chemical substance, regardless of physical state or concentration, through all intended operations of industrial; commercial, or consumer use.

"Waters of the United States" has the meaning set forth in 40 CFR 122.2.

"Work area" means a room or defined space in a workplace where the PMN substances are manufactured, processed, or used and where employees are present.

"Workplace" means an establishment at one geographic location containing one or more work areas.

ATTACHMENT B

NOTICE OF TRANSFER
OF
TOXIC SUBSTANCES CONTROL ACT
SECTION 5(e) CONSENT ORDER

_____ _____

Company (Transferor) PMN Number

1. Transfer of Manufacture Rights. Effective on _____, the Company did sell or otherwise transfer to _____, ("Successor in Interest") the rights and liabilities associated with manufacture of the above-referenced chemical substance, which was the subject of a premanufacture notice ("PMN") and is governed by a Consent Order issued by the U.S. Environmental Protection Agency ("EPA") under the authority of §5(e) of the Toxic Substances Control Act ("TSCA," 15 U.S.C. §2604(e)).

2. Assumption of Liability. The Successor in Interest hereby certifies that, as of the effective date of transfer, all actions or omissions governed by the applicable Consent Order limiting manufacture, processing, use, distribution in commerce and disposal of the PMN substances, shall be the responsibility of the Successor in Interest. Successor in Interest also certifies that it is incorporated, licensed, or doing business in the United States in accordance with 40 CFR 720.22(a)(3).

3. Confidential Business Information. The Successor in Interest hereby:

___ reasserts,

___ relinquishes, or

___ modifies

all Confidential Business Information ("CBI") claims made by the Company, pursuant to Section 14 of TSCA and 40 CFR part 2, for the PMN substance(s). Where "reasserts" or "relinquishes" is indicated, that designation shall be deemed to apply to all such claims. Where "modifies" is indicated, such modification shall be explained in detail in an attachment to this Notice of Transfer. Information which has been previously disclosed to the public (e.g., a chemical identity that was not claimed as CBI by the original submitter) would not subsequently be eligible for confidential treatment under this Notice of Transfer.

TOXIC SUBSTANCES CONTROL ACT
SECTION 5(e) CONSENT ORDER

NOTICE OF TRANSFER
(continued)

Company (Transferor)	PMN Number
Signature of Authorized Official	Date
Printed Name of Authorized Official	
Title of Authorized Official	
Successor in Interest	
Signature of Authorized Official	Date
Printed Name of Authorized Official	
Title of Authorized Official	
Address	
City, State, Zip Code	

TOXIC SUBSTANCES CONTROL ACT
SECTION 5(e) CONSENT ORDER

NOTICE OF TRANSFER
(continued)

_____
Successor's Technical Contact

_____
Address

_____
City, State, Zip Code

_____
Phone

TSCA CONFIDENTIAL
BUSINESS INFORMATION
DOES NOT CONTAIN NATIONAL
SECURITY INFORMATION (E.O. 12065)